K120350

Section 5 **510(k) Summary**

NOV 1 2012

This 510(k) is being submitted in accordance with the requirements of CFR 807.92.

5.1 Administrative Information

Submitted by: AED Battery Exchange, LLC
1000 Brown Street, Suite #310
Wauconda, IL 60084
USA

Contact Person: Phone: Keith Hochhalter
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keith@aedbatteryexchange.com

Original Date Prepared: January 27, 2012
Additional Information Provided: April 4, 2012

5.2 Device Name and Classification:

Common/Generic	Name:	Box, Battery
Trade/Proprietary	Name:	Green4Life Battery
Classification Name:		Box, Battery, Non-Rechargeable Regulatory Class III, Product Code MKJ

5.3 Device Description:

The Green4Life Batteries are non-rechargeable battery packs utilized as the primary power source or as a standby or backup power source for Automated External Defibrillators (AEDs). These devices provide a means of supplying electrical power through the chemical reaction of lithium cells. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current required by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and discharge method. The goal of these battery packs is to provide a sufficient power source for AEDs for as long as possible under a specified range of environmental conditions.

The Green4Life Batteries are re-celled battery packs of those identified below in Predicate Devices.

5.4 Indications for Use:

To power AEDs for which the OEM battery pack was intended. Only qualified service personnel should evaluate, test, or install AED battery packs.

5.5 Predicated Devices:

Company	Device	510(k) #	Date Cleared
Cardiac Science	Replacement Battery 9141	K031987	7/30/2003
		K040438	7/1/2004
Cardiac Science	Replacement Battery 9146	K031987	7/30/2003
		K040438	7/1/2004
Philips	Replacement Battery ForeRunner BTI	K955628	9/10/1996
Philips	Replacement Battery HeartStart	K020715	11/8/2002
	FRX, Onsite/HomeAED (M5070)	K040904	9/16/2004
		K050004	2/25/2005
Philips	Replacement Battery HeartStart	K013425	1/14/2002
	FR2 (M3863)	K051632	10/5/2005
Philips	Replacement Battery HeartStart FR3 (989803150161)	K111693	10/28/2011
Defibtech	Replacement Battery DCF-200	K033896	6/16/2004
		K081259	6/15/2009
Physio Control	Replacement Battery Lifepak 500	K955854	11/4/1996

5.6 Substantial Equivalence:

The Green4Life Battery packs are re-celled battery packs of those identified above in Predicate Devices. Existing enclosures are opened, lithium cells are replaced with identical or equivalent, or superior cells, re-closed, reset if memory equipped, and tested. Therefore, the pack is typically the exact original equipment. Only the lithium cells are replaced within the original battery packs unless other components including the power rectifiers, thermal fuses, or current limit fuses are found faulty or damaged during cell removal. In these cases, components will be replaced with identical part number components.

5.7 Testing:

5.7.1 Performance Testing

The Green4Life Battery packs are re-celled packs manufactured as cleared devices. Cells are replaced with identical cells to those used by the OEM or equivalent in specifications over the full temperature range of AED operation. Each AED has an internal test of the battery to verify that it is capable of providing the necessary power to the AED. This self test is a good indicator that the replacement battery back is acceptable. Performance testing within the specific AED was conducted to verify that the replacement battery pack tested within limits and that reset of battery pack information when operated within the designated AED, for those packs equipped with memory devices, was acceptable.

5.7.2 Manufacturing Tests

Incoming inspection of lithium cells will include visual examination and internal resistance measurements on typical sampling plans for similar devices. Approved cells will be assembled into packs where they go through a 100% testing as follows, including an open circuit test, loaded test, and installed test.

Original Manufacturer	Model Number	Open Circuit Minimum Voltage @20 degrees C	Loaded Circuit Minimum Voltage @20 degrees C: L=load resistance, Vnom=nominal voltage output, Vmin=minimum measured voltage output
Cardiac Science	9141	For Vnom=6V, Vmin=6.0V For Vnom=12V, Vmin=12.0V	For Vnom=6V, L=8 ohms, Vmin=5.5V For Vnom=12V, L=15 ohms, Vmin=11.0V
Cardiac Science	9146	Vmin=12.0V	L=15 ohms, Vmin=11.0V
Philips	BT1	Vmin=18.0V	L=23 ohms, Vmin=16.6V
Philips	M5070 (FRX/Onsite)	Vmin=9.0V	L=11 ohms, Vmin=8.2V
Philips	M3863 (FR2)	Vmin=12.0V	L=15 ohms, Vmin=11.0V
Philips	989803150161 (FR3)	Vmin=12.0V	L=15 ohms, Vmin=11.0V
Defibtech	DCF-200	For Vnom=3V, Vmin=3.0V For Vnom=15V, Vmin=15.0V	For Vnom=3V,L=4 ohms, Vmin=2.7V For Vnom=15V,L=20 ohms, Vmin=13.8V
Physic Control	Lifepak 500	Vmin=12.0V	L-15 ohms, Vmin=11.0V

In addition to the above open circuit and load DC voltage tests, the battery packs will be installed into their corresponding AED for a final acceptance test. The battery pack must easily install into the AED and firmly lock into place as with the original battery pack. Upon installation the AEDs undergo an operational self test of the installed battery. Final battery pack acceptance testing requires a reported "pass" by the corresponding AED.

5.8 Conclusion:

AED Battery Exchange has demonstrated through evaluation and testing of the Green4Life Battery packs, that their re-celled battery packs are equivalent with respect to indications for use, technological characteristics, materials, form, fit, and function to the replacement battery packs commercially available for specific AEDs outlined in this submission. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided as section 15 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 1 2012

AED Battery Exchange, LLC
c/o Mr. Keith Hochhalter
1000 Brown Street, Suite #310
Wauconda, IL 60084

Re: K120350
Trade Name: Green4Life Battery with models M5070-ABE, M3863-ABE, BT1-ABE, 500-ABE, DCF-200-ABE, 9141-ABE and 9146-ABE (7 models total)
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: Undated
Received: October 19, 2012

Dear Mr. Hochhalter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120350

Device Name: Green4Life Batteries with the following models:

M5070-ABE, M3863-ABE, BT1-ABE, 500-ABE, DCF-200-ABE, 9141-ABE and 9146-ABE (7 models total).

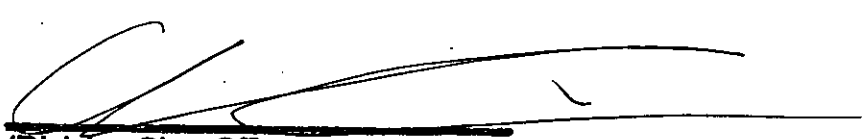
Indications for Use:

To provide power for the specific Automated External Defibrillators (AEDs) for which the original battery packs were designed and manufactured, in back-up and portable use.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120350